



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

FOAMTEC INTERNATIONAL CO., LTD 259/1, 259/2 and 259/3 Moo 3, Laemchabang Industrial Estate, Export Processing Zone, Toongsukhla, Sriracha, Chonburi 20230 Thailand

Holds Certificate Number:

MD 731871

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture of applicators, pads, sterile and non sterile swabs, sterile and non sterile wipers, foam components and plastic assemblies for use as, or a component of an active, non active or in-vitro diagnostic medical device.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-07-13 Latest Revision Date: 2022-11-23

bsi.



Effective Date: 2020-11-16 Expiry Date: 2023-11-15

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +66(2) 2944889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

Certificate No: MD 731871

Location

FOAMTEC INTERNATIONAL CO., LTD 259/1, 259/2 and 259/3 Moo 3, Laemchabang Industrial Estate, Export Processing Zone, Toongsukhla, Sriracha, Chonburi 20230 Thailand

FOAMTEC INTERNATIONAL CO., LTD 111/1 MOO 2, KM 56 of Phahonyothin Road, Lamsai, Wangnoi, Pranakornsriayutthaya 13170 Thailand

Registered Activities

The manufacture of applicators, pads, sterile and non sterile swabs, sterile and non sterile wipers, foam components and plastic assemblies for use as, or a component of an active, non active or in-vitro diagnostic medical device.

Distribution of applicators, pads, sterile and non sterile swabs, sterile and non sterile wipers, foam components and plastic assemblies for use as, or a component of an active, non active or in-vitro diagnostic medical device.

Original Registration Date: 2020-07-13 Latest Revision Date: 2022-11-23

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